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Comparison of the effect of negative pressure wound therapy with topical insulin application on wound healing in diabetic foot wounds versus NPWT alone

Dr Nandeesh M*
Associate professor, Department of General surgery, East Point College of Medical Sciences & Research Centre, Bangalore-560049
*Corresponding author

Dr Anitha TK
Associate professor, Department of Microbiology, East Point College of Medical Sciences & Research Centre, Bangalore-560049

Dr Shaik Mohammed Waseem
Senior Resident, Department of surgery, East Point College of Medical Sciences & Research Centre, Bangalore-560049

***Abstract*---**Introduction: Diabetic foot is an important and devastating complication of the Type II diabetes mellitus. This study was mainly undertaken to study the combination of NPWT along with topical insulin application and its effect on wound healing when compared to NPWT alone. Material and Methods: A prospective interventional study was undertaken in the Department of Surgery, Bengaluru. A total of 100 patients were divided equally between the two groups where one group received NPWT alone and another group received NPWT with topical insulin. The wounds in both the experimental and control groups were opened on the 7th, 15th and 30th day and compared using the BATES - JENSEN WOUND ASSESSMENT TOOL. The details were collected by using a predesigned proforma and analysed using Statistical Package for Social Services (SPSS ver 20). Results: Majority of the patients in both experimental and control groups were aged more than 60 years and were males. There was no statistically significant difference between the NPWT alone and NPWT with topical insulin groups. The BWAT scores improved over the follow up periods was statistically significant between NPWT alone group and NPWT with topical insulin groups during 7th day, 15th day and 30th day of follow up periods. Conclusion: The authors conclude that, the topical

insulin helps in faster healing of the diabetic foot wounds in patients with type II diabetes mellitus patients.
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***Keywords*---**Diabetic foot, Type II diabetes mellitus, topical insulin, NPWT, BWAT scores.

Introduction

Diabetes Mellitus is an important public health problem affecting one in every five Indians.[1]Type 2 Diabetes Mellitus carries both microvascular and macrovascular complications. They include cerebrovascular, cardiovascular and peripheral arterial disease, retinopathy, neuropathy and nephropathy. Diabetic foot is one of the significant and devastating complications of diabetes and is often defined as a foot affected by ulceration which is associated with neuropathy and/or peripheral arterial disease of the lower limb in a patient with diabetes.[2]

In this population, infections can progress very rapidly, with significant tissue damage from a combination of delayed presentation and compromised immune function. Vacuum-assisted closure is also referred to as micro deformational wound therapy (MDWT) or Negative Pressure Wound Therapy.[3]

During the inflammatory phase, negative pressure wound therapy removes infiltrating leukocytes, along with wound exudates while simultaneously inducing inflammation. It increases both the production and maturation of collagen. It has been demonstrated to cause a reduction in the wound surface area, volume and depth of the wound.

In diabetic foot ulcers, NPWT promotes granulation tissue formation and microbial clearance thus enabling a higher rate of limb salvage.It also leads to wound contracture, neo epithelisation and removes interstitial fluid when applied to wound edges. It prepares wounds to heal by secondary intention and helps wounds to be closed by reconstructive measures. It also acts as an ideal dressing to increase the chances of skin graft incorporation.

Insulin has been shown to have a positive effect on wound healing. Insulin-like growth factor which is very similar to the hormone insulin has been shown to promote the proliferation, migration and extracellular matrix excretion by keratinocytes, endothelial cells and fibroblasts and even promote the reformation of granulation tissue.[4]

As many studies are not available regarding the combination of NPWT along with topical insulin application and its effect on wound healing when compared to NPWT alone, hence this study was undertaken.

Material and Methods

A prospective interventional study was undertaken in the Department of Surgery, Bangalore. The estimated sample size on the basis of prevalence of 6.75% was approximately 100 cases which were divided into two equal groups. The patients

aged more than 18 years with well known diabetes status or newly diagnosed cases of diabetes with one or more-foot ulcers without accompanied osteomyelitis, patients who had given consent, patients with ankle brachial pressure index of more than 0.7 were included into the study. The patients with malignancies, active systemic infection, risk of bleeding, sites where there were large vascular structures were excluded from the study.

The wounds in both the experimental and control groupswere opened on the 7th, 15th and 30th day and compared using the BATES - JENSEN WOUND ASSESSMENT TOOL.[5]Under aseptic precautions, after inspecting the wound a thorough betadine and peroxide wash are given and the wound is debrided until fresh bleeding occurs from the wound surface.

First, the wound bed is sprayed with insulin (Human Actrapid 1 U/ cm2 of wound area) allowed to dry for 15 minutes and then covered with sterile gauze. The blood glucose levels are measured using a glucometer 10 minutes before and 1 hour after the application of topical insulin to ascertain that there are no episodes of hypoglycaemia. The wound bed is then covered with sterile sponges cut to the shape of the wound with a 16F Ryle's tube inserted between the sterile sponges.

The wound is then sealed with a sterile polyurethane sheet and confirmed that the whole setting is air tight. The Ryle's tube is then connected to a wall-mounted suction apparatus and the pressure is set at - 125 mm Hg and the suction is kept on for 20 minutes to 30 minutes in an hour. The dressing is opened every 5th day and the wound is inspected. Along with this culture is sent from the wound area.The data was collected in a predesigned proforma and compiled using Microsoft excel. The data was analysed using Statistical package for social services (SPSS ver 21).

Results

Table 1
Demographic characteristics of the study group

Demographic characteristics		NPWT n (%)	NPWT + Topical insulin n (%)
Age group	31 – 40 years	0	2 (4.0)
	41 – 50 years	5 (10.0)	6 (12.0)
	51 – 60 years	20 (40.0)	18 (36.0)
	More than 60 years	25 (50.0)	24 (48.0)
Sex	Male	41 (82.0)	39 (78.0)
	Female	9 (18.0)	11 (22.0)
Mode of onset	Post traumatic	28 (56.0)	28 (56.0)
	Spontaneous	22 (44.0)	22 (44.0)

This study had shown that, majority of the cases were aged above 60 years and were males in both NPWT alone and NPWT with topical insulin. Trauma was the main reason for the foot ulcers.

Table 2
Wound dimensions of the study group

Dimensions of wound (Mean ± SD)	NPWT	NPWT + Topical insulin	T value	P-value, Sig
Length (in cms)	7.16 ± 2.74	7.12 ± 3.15	0.068	0.946, NS
Width (in cms)	7.54 ± 2.0	6.96 ± 2.19	1.381	0.171, NS
Size (in cm^2) area	55.74 ± 28.74	52.16 ± 33.43	0.574	0.567, NS

The mean length of wound in NPWT group was 7.16 cms and NPWT with topical insulin was 7.12 cms. The mean width of the wound in NPWT was 7.54 cms and NPWT with topical insulin group was 6.96 cms. The mean size of the wound in NPWT group was 55.74 cm^2 and 52.16 cm^2 in NPWT with topical insulin. There was no statistically significant difference in length, width and size of the wound.

Table 3
Distribution of the study group according to BWAT score at different follow up intervals

BWAT score after dressing (Mean ± SD)	NPWT	NPWT + Topical insulin	T value	P-value, Sig
Baseline	47.2 ± 2.27	47.06 ± 2.31	0.306	0.76, NS
Day 7	43.46 ± 2.24	41.6 ± 2.3	4.107	0.000, Sig
Day 15	32.6 ± 2.46	27.04 ± 2.18	11.955	0.000, Sig
Day 30	27.06 ± 4.54	23.32 ± 3.82	4.454	0.000, Sig

The mean baseline BWAT score in NPWT group was 47.2 and NPWT with topical insulin was 47.06 which was not statistically significant. There was a statistically significant difference in BWAT scores between the NPWT and NPWT with topical insulin groups on day 7, day 15 and day 30 of follow up. The scores have declined drastically from baseline to 30 days of follow up but more marked in NPWT with topical insulin group.

Figure 1. Diabetic foot ulcer after NPWT

Discussion

This study was mainly undertaken in order to study the efficacy of NPWT and NPWT with topical insulin in diabetic foot patients. This study had shown that, majority of the patients in both NPWT alone and NPWT with topical insulin groups were aged more than 60 years and were males. These results were comparable with other studies.[6]

In this study the dimensions of wound were comparable between the NPWT alone group and NPWT with topical insulin group since length, width and size of the wound were not significantly different. A study by Stephen et al had shown that the wound size was significantly larger in normal saline group than the insulin group.[6] Ramarao et noted a significant reduction of mean ulcer area with higher percent in the topical insulin group than the normal saline group.[7] A study by Goenka et al had noted that the rate of healing was 130.2 mm^2 / week in the topical insulin group and 95.1 mm^2 in the normal saline group.[8]

BWAT scores have shown a significant improvement but more marked in NPWT with topical insulin group than the NPWT alone group. This difference was statistically significant between the NPWT alone and NPWT with topical insulin group 7 days, 15 days and 30 days of follow up. A very few studies compared these findings. Stephen et al had shown that, the mean Pressure Ulcer Scale for Healing (PUSH) scores were 10.52 in the normal saline group and 10.28 in the topical insulin group.[6]

Conclusion

This study had demonstrated that, there is a significant reduction of ulcer size in diabetic foot patients. The topical insulin helps in faster healing of the diabetic foot wounds and hence reduces the morbidity, duration of hospital stay and cost of treatment.

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